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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,053	01/16/2002	Lee L. Swanstrom	3395-US	2780

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APPLIED MEDICAL RESOURCES CORPORATION
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/053,053	SWANSTROM, LEE L.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10,12-19,21-40,42-50 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10,12-19,21-40,42-50 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 11/09/2009. Regarding the prior office action filed 08/18/2009, Swanstrom (U.S. Patent No. 6,626,919) does not qualify as prior art under 35 U.S.C. 102(e), since it is not filed by "another". New grounds of rejection are set forth below that replace Swanstrom (U.S. Patent No. 6,626,919) with **Swanstrom** (WO **99/33402**), which was published on 08/07/1999, and therefore qualifies as prior art under U.S.C. 102(b), since the present application was filed January 16, 2002.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 12, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al., hereinafter **"Lenker"** (U.S. Patent No. **6,350,278**) in view of **Swanstrom** (WO **99/33402**).

Lenker discloses a delivery device for positioning a intraluminal prosthesis in a vessel wall of an organ comprising an expansion assembly with proximal ends of struts **342** being free of mechanical connection that are captured within a cap or means for collapsing expansion assembly **344** in a first position, and

wherein said proximal ends are released from said cap in a second position, with means for dilating the expansion assembly and central strut **350** expands a portion of said implant against said vessel wall (Figures 23A-23B).

Lenker does not expressly disclose fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds said portion against said vessel wall, including a means for fastening

In Figures 4-7 Swanstrom teaches means for fastening including a fastener member **8** adapted to be inserted with an implant **3**, at least one flexible tie connector **9** extending from the fastener member, needle means **17** for containing said fastener member and flexible tie connector (needle **17** contains a portion of flexible tie connector at slot 19), means for driving said needle means through the exterior of said vessel wall to pierce said vessel wall and said implant, said means for driving including an endosurgical tool, push rod **20** or means for discharging said fastener member from said needle means into the interior of said implant, said at least one flexible tie connector including an external portion extending from said fastener member exteriorly of said vessel wall, and means for applying tensile force to said external portion of said at least one flexible tie connector, whereby said implant and said vessel wall are clamped together between said fastener member and said external portion of said at least one flexible tie connector (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a means for fastening the implant of Lenker to the vessel wall, as taught by Swanstrom, in order to prevent migration of the implant or

leaks and to effectively secure the implant to the target wall to prevent inadvertent disengagement (page 4 line 29 to page 5 line 12).

3. Claims 2, 15, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**) in view of **Swanstom** (WO **99/33402**), as applied to claim 1 above, and further in view of **Hughes et al.** (U.S. Patent No. **4,728,328**).

The combination of Lenker and Swanstrom disclose the limitations as shown above. The combination does not disclose the following limitations, but Hughes et al. as shown do:

• said implant comprises a tubular, sleeve-like component free of mechanical structure (Fig 1).

• wherein said tubular, sleeve-like component includes at least one cuff (14) formed at a proximal end thereof;

• wherein said tubular, sleeve-like component includes at least one cuff (14) formed at one end thereof;

• wherein said at least one cuff includes an end portion (18) of said tubular, sleeve-like component folded retroflexively to impinge on the exterior of said component (Fig 1);

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Swanstrom's implant assembly to include Hughes' tubular sleeve. Such a modification would ensure long-term stability of the implant and reduce infection.

4. Claims 3 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**), **Swanstom** (WO **99/33402**), and **Hughes et al.** (U.S. Patent No. **4,728,328**), as applied to claim 2 and 15 above, and further in view of **Cox et al.** (U.S. Pub. No. **2003/0023301**).

The combination of Lenker/Swanstrom/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Cox et al. as shown do:

• said removable expansion assembly is disposed to translate concentrically within said tubular, sleeve-like component free of mechanical structure (Fig 1)

• a catheter assembly having a first tube (Fig 1, #20);

• said first tube includes a lumen (Fig 1, #20) adapted to receive said tubular, sleeve- like component, said first tube having a diameter dimensioned so that the proximal end of said first tube engages said cuff in end-abutting relationship;

• said tubular, sleeve-like component is disposed in said lumen in a radially contracted state (Fig 1);

• said catheter assembly includes a second tube disposed for axial translation concentrically within said first tube (Fig. 1, #11), said second tube having a proximal end dimensioned to engage the distal end of said tubular, sleeve-like component in end-abutting relationship.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Swanstrom, and Hughes' implant assembly to include Cox's catheter and tubes. Such a modification would protect

the vessel from abrasion by the expansion member and force the implant out of the sleeve. The limitations following the phrases "adapted to" and "dimensioned to" are considered to be functional language and thus require nothing more than the ability to so perform.

5. Claims 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**) and **Swanstom** (WO **99/33402**), as applied to claim 1 above, and further in view of **Levinson et al.** (U.S. Patent No. **6,537,296**).

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** in view of **Swanstom** (WO 99/33402) and **Levinson et al.** (U.S. Patent No. **6,537,296**).

Lenker and Swanstrom disclose the claimed device except for the struts being urged in a proximal direction in order to thereby compress the peripheral struts axially by impinging on the proximal ends, and the expansion assembly being received within a confinement tube.

Levinson et al. teach a plurality of peripheral struts **10** with proximal ends (near **40**) and distal ends (near **46**), and a stop **16** mounted on a central strut **12** slidably disposed within said tube, wherein said stop is movable between a first position, wherein said proximal ends are abutting said stop, wherein the stop impinges on said proximal ends to compress struts axially, and a second position wherein said proximal ends are not abutting said stop, a means for dilating **44** said expansion assembly against said vessel wall and means for collapsing said

expansion assembly (Figures 27A-C). The expansion assembly may be received within a confinement tube or catheter **48** (Figure 9). It would have been obvious to one of ordinary skill in the art at the time of invention to provide struts being urged in a proximal direction in order to thereby compress the peripheral struts axially by impinging on the proximal ends, as taught by Levinson et al., to Lenker and Swanstrom in order to selectively collapse and expand the assembly if desired.

6. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**), **Swanstom** (WO **99/33402**), and **Hughes et al.** (U.S. Patent No. **4,728,328**), as applied to claim 2 above, and further in view of **Trescony et al.** (U.S. Patent No. **5,653,745**).

The combination of Lenker/Swanstrom/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Trescony et al. as shown do:

• said tubular sleeve-like component (Fig. 1, #10) includes means for increased longitudinal stiffness (col. 3, ln 56-67);

• wherein said means for increased longitudinal stiffness includes a plurality of stiffener struts or pleats (Fig. 1, #12) extending longitudinally in said tubular, sleeve-like component (Fig. 1).

NOTE: Trescony teaches pleats extending longitudinally (Fig 1). Due to the substantially similar structure of the reference and the Applicant's implant, the Examiner considers the pleats to increase longitudinal stiffness. Therefore, it

would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Swanstrom, and Hughes' implant assembly to include Trescony's pleats. Such a modification would provide longitudinal support reducing stretching, making the implant more durable.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**), **Swanstom** (WO **99/33402**), and **Hughes et al.** (U.S. Patent No. **4,728,328**), as applied to claim 25 above, and further in view of **Chevillon et al.** (U.S. Patent No. **6,248,116**) The combination of Lenker/Swanstrom/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but Chevillon et al. as shown do:

• further including at least one reinforcing band (Fig. 1, #140a) incorporated in said at least one cuff;

• said at least one reinforcing band is resiliently (col. 7, ln 1-3) biased to expand radially outwardly (Fig. 1, #140a).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Swanstrom, and Hughes' implant assembly to include Chevillon's bands. Such a modification would reinforce the implant against the vessel wall.

8. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**), **Swanstom** (WO **99/33402**), and

Hughes et al. (U.S. Patent No. **4,728,328**), as applied to claim 2 above, and further in view of **White et al.** (U.S. Pub. No. **2006/0015176**).

The combination of Lenker/Swanstrom/Hughes disclose the limitations as shown above. The combination does not disclose the following limitations, but White et al. as shown do:

• said implant has a Y-configuration (Fig 9);

• wherein one branching end of said Y-configuration comprises an elongated tubular leg (Fig. 9, #28);

• wherein one branching end of said Y-configuration comprises a short connector leg (Fig 9, #29).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker/Swanstrom/Hughes. Such a modification would be used for placement in a bifurcated blood vessel.

9. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**) in view of **Swanstom** (WO **99/33402**), as applied to claim 36 above, and further in view of **Haber et al.** (U.S. Patent No. **5,201,743**).

The combination of Lenker and Swanstrom disclose the limitations as shown above. The combination does not disclose the following limitations, but Haber et al. as shown do:

• said means for applying tensile force include means for winding said at least one flexible tie connector about a winding axis (Fig. 6, #118).

• said means for winding including a torque-limiting mechanism (Fig. 6; col. 4, ln 8-20);

• said means for winding includes an endosurgical tool (Fig 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Swanstrom's implant assembly to include Haber's means for winding. Such a modification would secure the fastener to the tissue.

10. Claims 40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lenker** (U.S. Patent No. **6,350,278**) in view of **Cox et al.** (U.S. Pub. No. **2003/0023301**).

Claim 40: Lenker discloses the limitations as shown above and further disclose:

• a plurality of peripheral struts (Fig. 23B, #342),

• said struts having a relaxed state in which said peripheral struts extend generally parallel to a longitudinal axis and are spaced angularly thereabout (Fig. 23B, #342),

• said peripheral struts include proximal ends, said proximal ends being free of mechanical connection (Fig 23B);

• means for urging (350) said peripheral struts to a bowed state; Lenker disclose urging mechanism (350) that is capable of urging the struts into a bowed state when pulled back against the struts (342); wherein

• said peripheral struts (342) expand radially outwardly from said longitudinal

axis, to thereby dilate said surgical implant (Fig. 23B, element P).

Lenker also discloses said plurality of peripheral struts #342 being removably disposed within said surgical implant, or within the lumen of the implant P (Figure 23B).

Claims 42-48: Lenker discloses the limitations as shown above and further disclose:

• said peripheral struts include like distal ends, said distal ends being secured together (Fig 23A).

• said means for urging said peripheral struts includes means for compressing said peripheral struts along said longitudinal axis to effect bowing of said peripheral struts radially outwardly from said longitudinal axis (Fig. 23B). Note that Lenker discloses urging mechanism (350) that is capable of urging the struts into a bowed state when pulled back against the struts (342);

• said means for compressing includes an end cap (344), said end cap including means for releasably impinging on said proximal ends of said peripheral struts (Fig 23A-B).

• a central strut (see Fig. 23A-B) extending parallel to said peripheral struts, said central strut being secured to said end cap (Fig. 23B, #344 and #350).

• means for translating said central strut distally to urge said end cap to impinge on said proximal ends of said peripheral struts and compress said peripheral struts axially (Fig 23B).

• said means for releasably impinging includes a recess formed in a distal surface of said end cap (Fig 23A).

• means for translating said peripheral struts distally (Fig. 23A-B) along said longitudinal axis to move said proximal ends of said peripheral struts distally with respect to said end cap (see Fig. 23A-B).

Claims 49-50: Lenker does not disclose the following limitations, but Cox et al. as shown do:

• a confinement tube (Fig. 1-3, #20), said confinement tube having a lumen dimensioned to receive said peripheral struts in a non-expanded, radially-collapsed state (see Fig. 1-3; paragraph [0042]);

• said confinement tube is translatable with respect to said peripheral struts to move said confinement tube selectively into concentric confinement of said peripheral struts (paragraph [0042]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's expansion assembly to include Cox's tube assembly. Such a modification would protect the vessel from abrasion by the expansion member.

The Examiner notes that although the Lenker reference discloses the implant within the expansion member, it is common in the art as shown by the Cox reference to dispose the implant on the exterior of the expansion member. Because the Lenker assembly is fully capable of expanding an implant, the Examiner considers the Cox reference to teach how this would be achieved.

Response to Arguments

11. Applicant's arguments with respect to claims 1-3, 10, 12-19, 21-40, 42-50, and 60 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant argues that the plurality of axial members **342** in Lenker (Figures 23A-23B) do not bow when the central shaft **350** is urged towards them since the axial members resist bowing to maintain the prosthesis **P** in a radially compressed configuration. However, this is the case only when the axial members **342** are maintained within the cap **344** (Figure 23A) and are not under any loading force. Since the axial members are disclosed as "resilient" members having a spring-loaded or flexible property (col. 11, line 66 to col. 12, line 10), it would be reasonable to contend that with enough pulling force of the central member **350** and the cap **344** against the axial members **342** with respect to the catheter body **348** the axial members would compress or bow radially outwards due to their flexible nature. Therefore, even though Lenker does not suggest that the axial members dilate the prosthesis in the bowed state, there is not a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. In regards to claim 40, the limitation of "said plurality of peripheral struts being removably disposed within said surgical implant," are no longer cited in Cox, but rather in Lenker, since Lenker's said plurality of peripheral struts **342**

are removably disposed within said surgical implant **P**, or released from the lumen of the implant **P** when the implant expands (Figure 23B).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734